UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INDUSTRIES LTD., TEVA NEUROSCIENCE, INC. and YEDA RESEARCH AND DEVELOPMENT CO. LTD.,

Plaintiffs,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, NOVARTIS AG, and MOMENTA PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 08 CV 7611 (BSJ)(JCF) ECF Case

PLAINTIFFS' ANSWER TO MOMENTA'S COUNTERCLAIMS

Plaintiffs Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceuticals Industries Ltd. ("Teva Ltd.), Teva Neuroscience, Inc. ("Teva Neuroscience"), and Yeda Research and Development Co. ("Yeda") (collectively, "Plaintiffs"), for their Answer to the Counterclaims of Defendant Momenta Pharmaceuticals, Inc. ("Momenta"), hereby respond to each of the numbered paragraphs thereof as follows:

THE PARTIES

- 1. Upon information and belief, admitted.
- 2. Admitted.
- 3. Admitted.
- 4. Admitted.

5. Plaintiffs admit that Yeda is a company duly registered under the laws of Israel and has a principal place of business is at P.O. Box 95, Rehovot, 76100, Israel. To the extent that the allegations go further, they are denied.

JURISDICTION AND VENUE

- 6. This is a statement of jurisdiction to which no response is required. To the extent that a response is required, Plaintiffs state that they do not contest the Court's jurisdiction over Momenta's Counterclaims.
- 7. This is a statement of venue to which no response is required. To the extent that a response is required, Plaintiffs state that they do not contest the propriety of this Court as venue for Momenta's Counterclaims.

MOMENTA'S COUNTERCLAIMS

Plaintiffs respond to paragraphs 8-123 of Momenta's Counterclaims in the respective paragraphs below:

FIRST COUNTERCLAIM (Declaratory Judgment of Noninfringement of the '098 Patent)

8. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint and paragraphs 1 through 7 of Plaintiffs' Answer to Momenta's Counterclaims. With respect to paragraphs 1-50 of Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims, Plaintiffs respond to each of the numbered paragraphs thereof as follows:

RESPONSE TO MOMENTA'S AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE (Failure to State a Claim)

(1) Denied.

SECOND AFFIRMATIVE DEFENSE (Laches/Waiver/Estoppel)

(2) Denied.

THIRD AFFIRMATIVE DEFENSE (Inequitable Conduct)

- (3) Denied.
- (4) Plaintiffs admit that glatiramer acetate, the active ingredient of Copaxone[®], is the acetate salts of a mixture of polypeptides composed of alanine, glutamic acid, lysine, and tyrosine. Plaintiffs admit that Dvora Teitelbaum, A. Meshorer, T. Hirschfeld, Ruth Arnon and M. Sela are listed as co-authors in the publication entitled "Suppression of experimental allergic encephalomyelitis by a synthetic polypeptide," Eur. J. IMMUNOL, 1:242 (1971), and state that the contents of this publication are apparent on its face. Plaintiffs admit that Dvora Teitelbaum, Ruth Arnon and Michael Sela are listed, among other individuals, as co-inventors of the '098, '539, '430, '847, '589, '476, '161, '808 and '898 patents. To the extent that the allegations go further or are inconsistent, they are denied.
- (5) Plaintiffs admit that U.S. Patent No. 3,849,550 ("the '550 patent") lists Dvora Teitelbaum, Ruth Arnon and Michael Sela as co-inventors, that on its face the '550 patent issued from U.S. Patent Application No. 240,244 ("the '244 application"), filed on March 31, 1972, and that the '244 application claims priority to Israel Application No. 36,670, filed on April 21, 1971. Plaintiffs admit that on its face the '550 patent issued on November 19, 1974, and expired before May 1994. Plaintiffs further state that the contents of the '550 patent are apparent on its face. To the extent that the allegations go further or are inconsistent, they are denied.
- (6) Plaintiffs admit that a dalton is a unit of mass, and that a kilodalton ("kDa") is 1000 Daltons. Plaintiffs state that the contents and authorship of the references Abramsky et al., Effect Of A Synthetic Polypeptide (Cop 1) On Patients With Multiple Sclerosis And With Acute

Disseminated Encephalomyelitis, 31 J. NEUROL. SCI. 433 (1977); Arnon, The Development Of Cop-1 (Copaxone®), An Innovative Drug For The Treatment Of Multiple Sclerosis: Personal Reflections, 50 IMMUNOL. LETT. 1 (1996) ("Arnon"); Bornstein, et al., Multiple Sclerosis: Trial of a Synthetic Polypeptide, 11 Ann. Neurol. 317 (1982); Bornstein et al., A Pilot Trial of Cop-1 in Exacerbating-Remitting Multiple Sclerosis, 317 New Eng. J. Med. 408 (1987) ("Bornstein 1987") are apparent on their faces. To the extent that the allegations go further or are inconsistent, they are denied.

- (7) Plaintiffs state that the contents of Arnon and Johnson et al., Copolymer-1 Reduces Relapse Rate and Improves Disability in Relapsing-Remitting Multiple Sclerosis, Neurology, 45: 1268 (1995) ("Johnson") are apparent on their faces. To the extent that the allegations go further or are inconsistent, they are denied.
- (8) Plaintiffs admit that U.S. Application No. 08/248,037 was filed on May 24, 1994 and is the earliest claimed priority application on the faces of the '098, '539, '430, '847, '589, '476, '161, '808 and '898 patents. To the extent the allegations go further or are inconsistent, they are denied.
- (9) Plaintiffs state that the regulations set forth in the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. are apparent on their faces. To the extent that the allegations go further or are inconsistent, they are denied.
- (10) Plaintiffs state that the legislative histories and contents of the Drug Price

 Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") and the Medicare

 Prescription Drug, Improvement, and Modernization Act of 2003 are apparent on their faces. To
 the extent that the allegations go further or are inconsistent, they are denied.

- (11) Plaintiffs state that the regulations set forth in 21 U.S.C. §§ 301 et seq. are apparent on their faces, and deny the remaining allegations to the extent they go further or are inconsistent.
- (12) Plaintiffs state that the regulations set forth in 21 U.S.C. §§ 301 et seq. are apparent on their faces, and deny the remaining allegations to the extent they go further or are inconsistent.
- (13) Plaintiffs state that the regulations set forth in 21 U.S.C. §§ 301 et seq. are apparent on their faces, and deny the remaining allegations to the extent they go further or are inconsistent.
- (14) Plaintiffs state that the regulations set forth in 21 U.S.C. §§ 301 et seq. are apparent on their faces, and deny the remaining allegations to the extent they go further or are inconsistent.
- (15) Plaintiffs state that the regulations set forth in 21 U.S.C. §§ 301 et seq. are apparent on their faces, and deny the remaining allegations to the extent they go further or are inconsistent.
- (16) Plaintiffs state that the regulations set forth in 21 U.S.C. §§ 301 et seq. are apparent on their faces, and deny the remaining allegations to the extent they go further or are inconsistent.
- (17) Plaintiffs admit that Teva USA submitted a New Drug Application ("NDA") for slowing progression of disability and reducing frequency of relapse in patients with relapsing-remitting MS with Copolymer-1 to the FDA on June 14, 1995. To the extent that the allegations go further or are inconsistent, they are denied.

- (18) Plaintiffs admit that the '550 patent is assigned on its face to Yeda and expired before May 1994. Plaintiffs admit that NDA No. 20-622 was submitted to the FDA on June 14, 1995. Plaintiffs state that the contents of the patents claiming priority to U.S. Application No. 08/248,037 are apparent on their faces. To the extent that the allegations go further or are inconsistent, they are denied.
 - (19) Denied.
- (20) Plaintiffs admit that Teva USA submitted NDA No. 20-622 seeking approval to market glatiramer acetate as Copaxone® for slowing progression of disability and reducing the frequency of relapse in patients with relapse-remitting MS. Plaintiffs state that the contents of the Review and Evaluation of Pharmacology and Toxicology Data from NDA No. 20-622 dated February 21, 1995 ("February 21, 1995 Review") are apparent on its face. To the extent that the allegations go further or are inconsistent, they are denied.
- (21) Plaintiffs state that the contents of the February 21, 1995 Review and the Review and Evaluation of Clinical Data from NDA No. 20-622 dated December 5, 1995 ("December 5, 1995 Review") are apparent on their faces. To the extent that the allegations go further or are inconsistent, they are denied.
- (22) Plaintiffs state that the contents of Johnson are apparent on its face, and deny the remaining allegations to the extent they go further or are inconsistent.
- (23) Plaintiffs state that the contents of the Summary Basis of Approval for NDA No. 20-622, the Review and Evaluation of Pharmacology Toxicology Data for NDA No. 20-622 (undated), and the Review and Evaluation of Clinical Data: Safety for NDA No. 20-622, dated January 30, 1996 are apparent on their faces. To the extent that the allegations go further or are inconsistent, they are denied.

- (24) Plaintiffs admit that Ruth Arnon, Dvora Teitelbaum and Michael Sela are listed as co-authors in Bornstein 1987 and that they are listed, among other individuals, as co-inventors of the '098, '539, '430 and '847 patents. Plaintiffs state that the contents of Bornstein 1987 are apparent on its face. To the extent that the allegations go further or are inconsistent, they are denied.
- (25) Plaintiffs admit that the FDA approved NDA No. 20-622 on December 20, 1996, and refer to the Summary Basis of Approval for NDA No. 20-622. To the extent that the allegations go further or are inconsistent, they are denied.
 - (26) Denied.
- (27) Plaintiffs state that the prosecution history of the '098 patent is apparent on its face, and deny the remaining allegations to the extent they go further or are inconsistent.
- (28) Plaintiffs state that the prosecution history of the '539 patent is apparent on its face, and deny the remaining allegations to the extent they go further or are inconsistent.
- (29) Plaintiffs state that the prosecution history of the '847 patent is apparent on its face, and deny the remaining allegations to the extent they go further or are inconsistent.
- (30) Plaintiffs are without knowledge or information as to what Momenta intends by "substantially identical" and therefore deny the allegations in the first sentence of this paragraph. Plaintiffs state that the contents of the specifications of the '098, '539, '430 and '847 patents are apparent on their faces. To the extent that the allegations go further or are inconsistent, they are denied.
- (31) Plaintiffs state that the prosecution histories of the '476 and '161 patents are apparent on their faces. Plaintiffs admit that the '476, '161, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, now abandoned, and that the '476,

'161, '098, '539, '430 and '847 patents are currently scheduled to expire on May 24, 2014. To the extent that the allegations go further or are inconsistent, they are denied.

- (32) Plaintiffs state that the prosecution history of the '589 patent is apparent on its face. Plaintiffs admit that the '589, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, now abandoned, and that the '589, '098, '539, '430 and '847 patents are currently scheduled to expire on May 24, 2014. To the extent that the allegations go further or are inconsistent, they are denied.
 - (33) Denied.
 - (34) Denied.
 - (35) Denied.
 - (36) Denied.
 - (37) Denied.
 - (38) Denied.
 - (39) Denied.

FOURTH AFFIRMATIVE DEFENSE (Unclean Hands)

(40) Denied.

FIFTH AFFIRMATIVE DEFENSE (Patent Misuse)

(41) Denied.

SIXTH AFFIRMATIVE DEFENSE ('098 Patent—Noninfringement)

(42) Denied.

SEVENTH AFFIRMATIVE DEFENSE ('098 Patent—Invalidity)

(43) Denied.

<u>EIGHTH AFFIRMATIVE DEFENSE</u> ('539 Patent—Noninfringement)

(44) Denied.

NINTH AFFIRMATIVE DEFENSE ('539 Patent—Invalidity)

(45) Denied.

<u>TENTH AFFIRMATIVE DEFENSE</u> ('430 Patent—Noninfringement)

(46) Denied.

ELEVENTH AFFIRMATIVE DEFENSE ('430 Patent—Invalidity)

(47) Denied.

TWELFTH AFFIRMATIVE DEFENSE ('847—Noninfringement)

(48) Denied.

<u>THIRTEENTH AFFIRMATIVE DEFENSE</u> ('847 Patent—Invalidity)

(49) Denied.

FOURTEENTH AFFIRMATIVE DEFENSE (Reservation of Rights)

- (50) Plaintiffs are without sufficient information to form a belief as to the truth of the allegations of this paragraph, and therefore deny them. The second sentence of this paragraph is an alleged reservation of rights to which no response is required.
 - 9. Denied.

10. Plaintiffs admit that an actual controversy exists between Plaintiffs and Momenta sufficient to warrant entry of a judgment by the Court that Momenta infringes one or more claims of the '098 patent, and deny that Momenta is entitled to any of the relief it seeks.

SECOND COUNTERCLAIM (Declaratory Judgment of Invalidity and Unenforceability of '098 Patent)

- 11. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 10 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 12. Denied.
 - 13. Denied.
 - 14. Denied.
 - 15. Denied.
- 16. Plaintiffs admit that an actual controversy exists between Plaintiffs and Momenta sufficient to warrant entry of a judgment by the Court that the '098 patent is valid and enforceable, and deny that Momenta is entitled to any of the relief it seeks.

THIRD COUNTERCLAIM (Declaratory Judgment of Noninfringement of '539 Patent)

- 17. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 16 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 18. Denied.

19. Plaintiffs admit that an actual controversy exists between Plaintiffs and Momenta sufficient to warrant entry of a judgment by the Court that Momenta infringes one or more claims of the '098 patent, and deny that Momenta is entitled to any of the relief it seeks.

FOURTH COUNTERCLAIM (Declaratory Judgment of Invalidity and Unenforceability of '539 Patent)

- 20. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 19 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 21. Denied.
 - 22. Denied.
 - 23. Denied.
 - 24. Denied.
- 25. Plaintiffs admit that an actual controversy exists between Plaintiffs and Momenta sufficient to warrant entry of a judgment by the Court that the '539 patent is valid and enforceable, and deny that Momenta is entitled to any of the relief it seeks.

FIFTH COUNTERCLAIM (Declaratory Judgment of Noninfringement of '430 Patent)

- 26. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 25 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 27. Denied.

28. Plaintiffs admit that an actual controversy exists between Plaintiffs and Momenta sufficient to warrant entry of a judgment by the Court that Momenta infringes one or more claims of the '430 patent, and deny that Momenta is entitled to any of the relief it seeks.

<u>SIXTH COUNTERCLAIM</u> (Declaratory Judgment of Invalidity and Unenforceability of '430 Patent)

- 29. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 28 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 30. Denied.
 - 31. Denied.
 - 32. Denied.
 - 33. Denied.
- 34. Plaintiffs admit that an actual controversy exists between Plaintiffs and Momenta sufficient to warrant entry of a judgment by the Court that the '430 patent is valid and enforceable, and deny that Momenta is entitled to any of the relief it seeks.

<u>SEVENTH COUNTERCLAIM</u> (Declaratory Judgment of Noninfringement of '847 Patent)

- 35. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 34 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 36. Denied.

37. Plaintiffs admit that an actual controversy exists between Plaintiffs and Momenta sufficient to warrant entry of a judgment by the Court that Momenta infringes one or more claims of the '847 patent, and deny that Momenta is entitled to any of the relief it seeks.

EIGHTH COUNTERCLAIM (Declaratory Judgment of Invalidity and Unenforceability of '847 Patent)

- 38. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 37 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 39. Denied.
 - 40. Denied.
 - 41. Denied.
 - 42. Denied.
- 43. Plaintiffs admit that an actual controversy exists between Plaintiffs and Momenta sufficient to warrant entry of a judgment by the Court that the '847 patent is valid and enforceable, and deny that Momenta is entitled to any of the relief it seeks.

NINTH COUNTERCLAIM (Declaratory Judgment of Noninfringement of U.S. Patent No. 5,981,589)

44. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 43 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.

- 45. Plaintiffs admit that the '589 patent is entitled "Copolymer-1 Improvements in Compositions of Copolymers," issued on November 9, 1999, and is assigned to Yeda. Plaintiffs deny the remaining allegations in this paragraph.
- 46. Plaintiffs admit that Teva Ltd. is the exclusive licensee of the '589 patent, and deny the remaining allegations in this paragraph.
- 47. Plaintiffs admit that the '589, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, now abandoned, and that the '589, '098, '539, '430 and '847 patents are currently scheduled to expire on May 24, 2014. To the extent that the allegations go further or are inconsistent, they are denied.
- 48. Plaintiffs admit that the '589, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, and state that the contents of the specifications of the '589, '098, '539, '430 and '847 patents are apparent on their faces. Plaintiffs are without knowledge or information as to what Momenta intends by "virtually identical" and therefore deny the remaining allegations in this paragraph.
- Plaintiffs admit that the '098, '539, '430, '847 and '589 patents are listed in the FDA's Orange Book for NDA 20-622, and that the listings meet all statutory and regulatory requirements. To the extent that the allegations are inconsistent, they are denied.
 - 50. Denied.
- 51. Plaintiffs admit that they have not granted Momenta a covenant not to sue with respect to the '589 patent. To the extent that the allegations go further, they are denied.
 - 52. Denied.
- 53. Plaintiffs do not contest the Court's jurisdiction over Momenta's Ninth Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

TENTH COUNTERCLAIM

(Declaratory Judgment of Invalidity and Unenforceability of U.S. Patent No. 5,981,589)

- 54. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 53 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 55. Denied.
 - 56. Denied.
 - 57. Denied.
- 58. Plaintiffs do not contest the Court's jurisdiction over Momenta's Tenth Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

ELEVENTH COUNTERCLAIM (Declaratory Judgment of Noninfringement of U.S. Patent No. 6,342,476)

- 59. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 58 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
- 60. Plaintiffs admit that the '476 patent is entitled "Copolymer-1 Improvements in Compositions of Copolymers," issued on January 29, 2002, and is assigned to Yeda. Plaintiffs deny the remaining allegations in this paragraph.
- 61. Plaintiffs admit that Teva Ltd. is the exclusive licensee of the '476 patent, and deny the remaining allegations in this paragraph.
- 62. Plaintiffs admit that the '476, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, now abandoned, and that the '476, '098, '539, '430 and

'847 patents are currently scheduled to expire on May 24, 2014. To the extent that the allegations go further or are inconsistent, they are denied.

- 63. Plaintiffs admit that the '476, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, and state that the contents of the specifications of the '476, '098, '539, '430 and '847 patents are apparent on their faces. Plaintiffs are without knowledge or information as to what Momenta intends by "virtually identical" and therefore deny the remaining allegations in this paragraph.
- 64. Plaintiffs admit that the '098, '539, '430, '847 and '476 patents are listed in the FDA's Orange Book for NDA 20-622, and that the listings meet all statutory and regulatory requirements. To the extent that the allegations are inconsistent, they are denied.
 - 65. Denied.
- 66. Plaintiffs admit that they have not granted Momenta a covenant not to sue with respect to the '476 patent. To the extent that the allegations go further, they are denied.
 - 67. Denied.
- 68. Plaintiffs do not contest the Court's jurisdiction over Momenta's Eleventh Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

TWELFTH COUNTERCLAIM (Declaratory Judgment of Invalidity and Unenforceability of U.S. Patent No. 6,342,476)

- 69. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 68 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 70. Denied.
 - 71. Denied.

- 72. Denied.
- 73. Plaintiffs do not contest the Court's jurisdiction over Momenta's Twelfth Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

THIRTEENTH COUNTERCLAIM (Declaratory Judgment of Noninfringement of U.S. Patent No. 6,362,161)

- 74. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 73 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
- 75. Plaintiffs admit that the '161 patent is entitled "Copolymer-1 Improvements in Compositions of Copolymers," issued on March 26, 2002, and is assigned to Yeda. Plaintiffs deny the remaining allegations in this paragraph.
- 76. Plaintiffs admit that Teva Ltd. is the exclusive licensee of the '161 patent, and deny the remaining allegations in this paragraph.
- 77. Plaintiffs admit that the '161, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, now abandoned, and that the '161, '098, '539, '430 and '847 patents are currently scheduled to expire on May 24, 2014. To the extent that the allegations go further or are inconsistent, they are denied.
- 78. Plaintiffs admit that the '161, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, and state that the contents of the specifications of the '161, '098, '539, '430 and '847 patents are apparent on their faces. Plaintiffs are without knowledge or information as to what Momenta intends by "virtually identical" and therefore deny the remaining allegations in this paragraph.

- 79. Plaintiffs admit that the '098, '539, '430, '847 and '161 patents are listed in the FDA's Orange Book for NDA 20-622, and that the listings meet all statutory and regulatory requirements. To the extent that the allegations are inconsistent, they are denied.
 - 80. Denied.
- Plaintiffs admit that they have not granted Momenta a covenant not to sue with respect to the '161 patent. To the extent that the allegations go further, they are denied.
 - 82. Denied.
- 83. Plaintiffs do not contest the Court's jurisdiction over Momenta's Thirteenth Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

FOURTEENTH COUNTERCLAIM (Declaratory Judgment of Invalidity and Unenforceability of U.S. Patent No. 6,362,161)

- 84. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 83 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 85. Denied.
 - 86. Denied.
 - 87. Denied.
- 88. Plaintiffs do not contest the Court's jurisdiction over Momenta's Fourteenth Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

FIFTEENTH COUNTERCLAIM (Declaratory Judgment of Noninfringement of U.S. Patent No. 5,800,808)

89. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 88 of Plaintiffs' Answer to Momenta's Counterclaims, and

paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.

- 90. Plaintiffs admit that the '808 patent is entitled "Copolymer-1 Improvements in Compositions of Copolymers," issued on September 1, 1998, and is assigned to Yeda. Plaintiffs deny the remaining allegations in this paragraph.
- 91. Plaintiffs admit that Teva Ltd. is the exclusive licensee of the '808 patent, and deny the remaining allegations in this paragraph.
- 92. Plaintiffs admit that the '808, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, now abandoned, and that the '808 patent is currently scheduled to expire on September 1, 2015. To the extent that the allegations go further or are inconsistent, they are denied.
- 93. Plaintiffs admit that the '808, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, and state that the contents of the specifications of the '808, '098, '539, '430 and '847 patents are apparent on their faces. Plaintiffs are without knowledge or information as to what Momenta intends by "virtually identical" and therefore deny the remaining allegations in this paragraph.
 - 94. Denied.
- 95. Plaintiffs admit that they have not granted Momenta a covenant not to sue with respect to the '808 patent. To the extent that the allegations go further, they are denied.
 - 96. Denied.
- 97. Plaintiffs do not contest the Court's jurisdiction over Momenta's Fifteenth Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

SIXTEENTH COUNTERCLAIM

(Declaratory Judgment of Invalidity and Unenforceability of U.S. Patent No. 5,800,808)

- 98. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 97 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 99. Denied.
 - 100. Denied.
 - 101. Denied.
- 102. Plaintiffs do not contest the Court's jurisdiction over Momenta's Sixteenth Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

SEVENTEENTH COUNTERCLAIM (Declaratory Judgment of Noninfringement of U.S. Patent No. 6,048,898)

- 103. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 102 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
- 104. Plaintiffs admit that the '898 patent is entitled "Copolymer-1 Improvements in Compositions of Copolymers," issued on April 11, 2000, and is assigned to Yeda. Plaintiffs deny the remaining allegations in this paragraph.
- 105. Plaintiffs admit that Teva Ltd. is the exclusive licensee of the '898 patent and deny the remaining allegations in this paragraph.
- 106. Plaintiffs admit that the '898, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, now abandoned, and that the '898, '098, '539, '430, and

'847 patents are currently scheduled to expire on May 24, 2014. To the extent that the allegations go further or are inconsistent, they are denied.

- 107. Plaintiffs admit that the '898, '098, '539, '430 and '847 patents claim priority to U.S. Patent Application No. 08/248,037, and state that the contents of the specifications of the '898, '098, '539, '430 and '847 patents are apparent on their faces. Plaintiffs are without knowledge or information as to what Momenta intends by "virtually identical" and therefore deny the remaining allegations in this paragraph.
 - 108. Denied.
- 109. Plaintiffs admit that they have not granted Momenta a covenant not to sue with respect to the '898 patent. To the extent that the allegations go further, they are denied.
 - 110. Denied.
- 111. Plaintiffs do not contest the Court's jurisdiction over Momenta's Seventeenth Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

<u>EIGHTEENTH COUNTERCLAIM</u> (Declaratory Judgment of Invalidity and Unenforceability of U.S. Patent No. 6,048,898)

- 112. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 111 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.
 - 113. Denied.
 - 114. Denied.
 - 115. Denied.
- 116. Plaintiffs do not contest the Court's jurisdiction over Momenta's Eighteenth Counterclaim, and deny that Momenta is entitled to any of the relief it seeks.

NINETEENTH COUNTERCLAIM (False Marking under 35 U.S.C. § 292)

117. Plaintiffs reallege and incorporate by reference paragraphs 1 through 91 of the Complaint, paragraphs 1 through 116 of Plaintiffs' Answer to Momenta's Counterclaims, and paragraphs 1-50 of Plaintiffs' response to Momenta's Affirmative Defenses, incorporated by reference in Momenta's Counterclaims.

- 118. Denied.
- 119. Denied.
- 120. Denied.
- 121. Denied.
- 122. Denied.
- 123. Denied.

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Momenta and that this Court:

- 1) dismiss Momenta's Counterclaims with prejudice;
- 2) grant Plaintiffs the relief they request in their Complaint;
- 3) award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: December 8, 2008

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CERTIFICATE OF SERVICE

I hereby certify that on December 8, 2008, I caused copies of the foregoing *Plaintiffs'*Answer to Momenta's Counterclaims to be served on the following counsel of record by the manner specified below:

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